

§ 520.2345

(c) *Conditions of use*—(1) *Amount*. Administer one tablet orally per 4 pounds of body weight.¹

(2) *Indications for use*. Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.¹

(3) *Limitations*. Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian.¹

[43 FR 60895, Dec. 29, 1978]

§ 520.2345 Tetracycline oral dosage forms.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) *Specifications*. Each capsule contains 50, 100, 125, 250, or 500 milligrams of tetracycline hydrochloride.

(b) *Sponsor*. See § 510.600(c) of this chapter for identification of the sponsors:

(1) To No. 000009: 250 milligrams per capsule.

(2) To No. 000069: 125, 250, and 500 milligrams per capsule.

(3) To No. 000115: 50, 100, 250, and 500 milligrams per capsule.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use*. Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations*. Administer orally; continue treatment until symptoms of the disease have subsided and the temperature is normal for 48 hours; not for use in animals raised for food produc-

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

21 CFR Ch. I (4–1–02 Edition)

tion; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 59365, Nov. 17, 1994; 63 FR 5255, Feb. 2, 1998]

§ 520.2345b Tetracycline tablets.

(a) *Specifications*. Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor*. For 100, 250, or 500 milligrams per tablet, see No. 000069 in § 510.600(c) of this chapter. For 250 milligrams per tablet, see No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use*. Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(3) *Limitations*. Administer orally; continue treatment until symptoms of the disease have subsided and temperature is normal for 48 hours; not for use in animals raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37327, Aug. 18, 1992]

§ 520.2345c Tetracycline boluses.

(a) *Specifications*. Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsors*. See No. 010042 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See No. 000009 in § 510.600(c) of this chapter for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See § 556.720 of this chapter.

(d) *Conditions of use*. *Calves*—(1) *Amount*. 10 milligrams per pound of body weight per day in divided doses.

(i) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp.

(ii) *Limitations*. Administer orally for 3 to 5 days; do not slaughter animals